

**REMARKS**

This Preliminary Amendment With Remarks is being filed with a Request for Continued Examination (RCE) pursuant to 37 C.F.R. §1.114. A final Office Action was issued on November 11, 2004 rejecting pending claims 1 and 3-24.

By this response, claims 1, 11, 17 and 21-24 are amended, and claim 10 canceled. Reconsideration and allowance are requested in light of the amendments and the following remarks.

Specifically, Applicants have amended claims 1, 17 and 21-24 to clarify the elements of the claimed apparatus and method, as per the Examiner's helpful suggestion. Claims 1, 17 and 21-24 now recite a maneuverable apparatus (or method involving a maneuverable apparatus) having a deflection member disposed within the lumen of the flexible elongate member, said deflection member having a partially cut-away distal end region. Support for this amendment can be found in canceled claim 10, as well as in the specification at page 10, lines 9-12; page 21, line 21 to page 22, line 4; and page 30, lines 16-24. No new matter is added.

Applicants have canceled claim 10.

Applicants have also amended claim 11 to correct the dependency.

**Rejections under 35 U.S.C. § 103(a)**

**Rejections of Claims 1, 3-12, 15-21 and 23 as being Unpatentable over Kittrell in view of Heaven**

In the final office action, the Examiner continued to reject claims 1, 3-12, 15-21 and 23 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent 5,104,392 to Kittrell et al., in view of U.S. Patent No. 5,306,245 to Heaven. Specifically, the Examiner stated:

Claims 1, 3-12, 15, 16 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kittrell et al in combination with Heaven. Kittrell et al teach a device as claimed except for the particular deflection member. Heaven

teaches a deflection member (see figure 1) which has an outer sheath (14), a cut out and, when viewed in profile, an hourglass shape wherein the width of the cut away portion is less than the diameter of the non-cut away portion. It would have been obvious to insert the device of Kittrell et al into the device of Heaven or to employ the elongate and the deflection member of Heaven in the device of Kittrell et al in place of, for example, element 140 in figure 14, since Kittrell et al envision a wide variety of deflection mechanisms; to provide multiple deflection members to allow deflection in multiple directions; and to form the deflection member so as to run from the proximal end of the catheter, since this would provide greater strength as shown by Heaven, thereby rendering the cutout at the distal end of the deflection member, and to form the member or surround the member with a fluoropolymer, since these are notorious for use in catheters and provide a lubricious surface, official notice which has already been taken, and to provide the particular location of the cutout, since this is not critical and provides no unexpected result, thus producing a device such as claimed.

Claims 17-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heaven in combination with Kittrell et al. The teachings of Heaven and Kittrell et al and the motivation for modification and combination thereof are essentially those already set forth above. It would have been obvious to the artisan of ordinary skill to repeatedly advance the fiber device of Kittrell et al when it is inserted through the tubular member of Heaven, since Kittrell et al specify the device is to be advanced through the lumen until the obstruction is removed, thus producing method such as claimed.

For the following reasons, Applicants respectfully request reconsideration and withdrawal of the Examiner's rejections.

### Applicants' Invention

Applicants provide a device and method for treating body tissues by delivering therapeutic energy directly into a target tissue while minimizing the effects on the surrounding tissue. Specifically, Applicants' invention is based, at least in part, on the discovery that the attachment of a *partially cut-away*, deflection member to the distal end of a flexible elongate member, e.g., a catheter, provides a means to bend, distort, or deform the flexible elongate member to a desired position. As a consequence of this maneuverability, an energy beam can be directed onto/into a specific target site, e.g., an anatomically important region, for treatment.

FIG. 24 represents one embodiment of a steerable catheter having a deflection member 20 that is partially cut away for a portion of its distal length. The cut away portion can rotate about the longitudinal axis of deflection member 20 at positions A and B, for example, as shown in FIGS. 24A and B, thus permitting the catheter to bend in a complex manner. Non-planar deflection, as shown, can be desirable in navigating within the circulatory system and/or the heart itself.

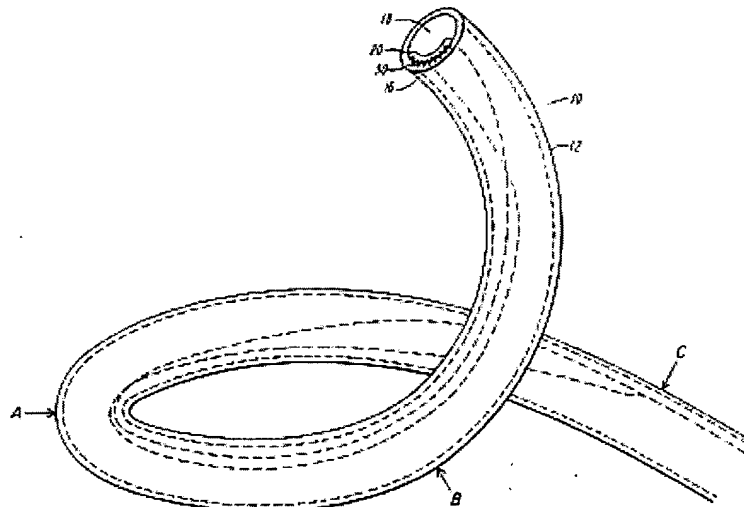


FIG. 24



*Kittrell in view of Heaven Does Not Disclose the Recitations of Applicants' Claims*

Applicants' claims 1, 3-12, 15-21 and 23 recite a maneuverable apparatus (or method involving a maneuverable apparatus) having a deflection member disposed within the lumen of the flexible elongate member, said deflection member having a partially cut-away distal end region.

Kittrell discloses a catheter for insertion into an artery via a conventional steering mechanism, that is, by control wires, balloons, or by a guide catheter. As noted by the Examiner, Kittrell does not recite a maneuverable apparatus having a deflection member having a partially cut-away distal end region.

Heaven does not remedy the deficiencies of Kittrell. Heaven teaches a tubular member having a cut-out on one side and a control wire on the opposite side. Contrary to any assertions by the Examiner, the tubular member is in no way equivalent to the deflection member taught by Applicants. The tubular member of Heaven is not used for *steering* the device. Rather, the cut-out is used to bias the device in one direction and a *conventional control wire is used for steering*. [Col. 5, lns. 18-20.]

Applicants' invention serves to improve upon the two-part system of Heaven by having a single deflection member with a partially cut-away shape. As noted in Applicants' description:

Currently, guidewires (pullwires) are used to direct catheters in a body lumen have several disadvantages. Guidewires have a tendency to break or release from the point of attachment in a catheter. Guidewires are generally not formed from the same material as the catheter body and therefore are not readily permanently affixed to the catheter body; hence the guidewire can inadvertently release. Another disadvantage of current guidewires is that they are often heated

by an energy source within the catheter during a treatment and transfer heat to areas away from the treatment site. Most guidewires are opaque and can be problematic in directing a catheter and locating the catheter to the proper treatment site.

[Page 3, Ins. 20-28.] Accordingly, because Kittrell in view of Heaven does not disclose the recitations of Applicants' claims 1, 3-12, 15-21 and 23, Applicants' claims 1, 3-12, 15-21 and 23 are allowable.

*There is no Motivation to Combine Kittrell with Heaven*

In addition to Kittrell with Heaven neither teaching nor suggesting all of the recitations of Applicants' claims, one having skill in the art would have no motivation to combine Kittrell with Heaven. The sole focus of Kittrell is to deliver a laser beam for percutaneous intravascular laser treatment via a laser catheter made of flexible inert plastic catheter material. It is this flexible material which allows the catheter to have access to the interior portions of the body to ablate tissue. In contrast, Heaven discloses a medical steering device which includes a tubular member, where a medical device such as a catheter, optical device, tissue removal device, cutting device, and other various surgical and diagnostic devices can be placed to provide access to the interior portions of the body.

Kittrell would have no use for a device which provides access to interior portions of the body because the design of Kittrell's device, specifically the fact that the catheter is made of flexible material, already allows for as such. Accordingly, because *Kittrell already solves the problem addressed by Heaven*, there would be no motivation for one skilled in the art to combine Kittrell with Heaven.

*Rejections of Claims 13 and 14 as being Unpatentable over Kittrell in view of Heaven, and further in view of Vassiliadis*

Claims 13 and 14 continue to be rejected over the same references above, and further in view of U.S. Patent No. 5,129,895 to Vassiliadis et al. Specifically, the Examiner stated:

Claims 13 and 14 are rejected under 3 U.S.C. 103(a) as being unpatentable over Kittrell et al in combination with Heaven as applied to claim 12 above, and further in view of Vassiliadis et al. Vassiliadis et al teach the use of a gold coating on a laser applicator. It would have been obvious to the artisan of ordinary skill to employ a gold coating, as taught by Vassiliadis, since this would protect tissue from unintended irradiation, thus producing a device such as claimed.

For the following reasons, Applicants respectfully request reconsideration and withdrawal of the Examiner's rejections.

*Kittrell in view of Heaven and further in view of Vassiliadis Does Not Disclose the Recitations of Applicants' Claims 13 and 14*

Applicants' claims 13 and 14 recite a maneuverable apparatus having a deflection member disposed within the lumen of the flexible elongate member, said deflection member having a partially cut-away distal end region, and further comprising a layer of reflective material affixed to said distal end of said elongate member.

As noted above, neither Kittrell nor Heaven recite a maneuverable apparatus having a deflection member disposed within the lumen of the flexible elongate member. Further, neither Kittrell nor Heaven teach or suggest a layer of reflective material affixed to the distal end region of the elongate member.

Vassiliadis does not remedy the deficiencies of Kittrell and Heaven. Nowhere does Vassiliadis teach or suggest a maneuverable apparatus having a deflection member disposed within the lumen of the flexible elongate member. Moreover, Vassiliadis does not teach or suggest a layer of reflective material affixed to the distal end region of the elongate member. Rather, Vassiliadis teaches a reflective surface coated on the outside of the tube to block the path of such reflected light. [Col. 4, lns. 34-49.] Thus, while Vassiliadis teaches a reflective material, the reflective material is located in an entirely different place, and has an entirely different purpose than that recited by Applicants'. Accordingly, because Kittrell in view of Heaven and in further with Vassiliadis does not disclose the recitations of Applicants' claims 13 and 14, Applicants' claims 13 and 14 are allowable.

*There is no Motivation to Combine Kittrell with Heaven and further with Vassiliadis*

In addition to neither Kittrell with Heaven and with Vassiliadis teaching or suggesting all of the recitations of Applicants' claims, one having skill in the art would have no motivation to combine Kittrell with Heaven, and further with Vassiliadis. As noted above, because Kittrell already solves the problem addressed by Heaven, there would be no motivation for one skilled in the art to combine Kittrell with Heaven. Further, one having skill in the art would have no motivation to combine Kittrell with Heaven and further with Vassiliadis because Vassiliadis is directed to an entirely different surgical procedure than Kittrell and Heaven.

As noted above, Kittrell is directed towards the insertion of a catheter into an artery to provide controlled delivery of a laser beam for percutaneous intravascular laser treatment of atherosclerotic disease, and the device of Heaven is used for conventional arthroscopic or laparoscopic procedures. [Col. 4, lns. 20-24.] In contrast, Vassiliadis is directed towards *performing a sclerostomy* (forming a small hole in the sclera of an eye) as a treatment of glaucoma.

Accordingly, because a sclerostomy is a very different procedure than the intravascular laser treatment of atherosclerotic disease or conventional arthroscopic or laparoscopic procedures, there would be no motivation for one skilled in the art to combine the teachings of Kittrell and Heaven, and further with Vassiliadis.

*Rejections of Claims 22 and 24 as being Unpatentable over Kittrell in view of Heaven, and further in view of Isner*

Claims 22 and 24 continue to be rejected over Kittrell in view of Heaven, and further in view of U.S. Patent No. 4,985,028 to Isner et al. Specifically, the Examiner stated:

Claims 22 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kittrell et al in combination with Heaven as applied to claims 17-21 are above, and further in view of Isner et al. Isner et al teach a method of treating tachycardia including inserting a catheter and inserting a fiber therein for applying laser energy to the foci responsible for the tachycardia. It would have been obvious to the artisan of ordinary skill to employ the

tachycardia treatment method of Isner et al in the surgical device placement method of Heaven, since Heaven teach that the device can be used with a variety of medical procedures thus producing a method such as claimed.

For the following reasons, Applicants respectfully request reconsideration and withdrawal of the Examiner's rejections.

*Kittrell in view of Heaven and further in view of Isner Does Not Disclose the Recitations of Applicants' Claims 22 and 24*

Applicants' claims 22 and 24 recite a method for treating or preventing atrial fibrillation by ablation, coagulation or phototherapeutic processes, comprising the steps of introducing a flexible elongate member proximate to atrial tissue, said flexible elongate member having a deflection member having a proximal end and a partially cut-away distal end region; manipulating said deflection member longitudinally relative to said elongate member, thereby causing said distal end of said elongate member to bend; positioning a slidable conductor through said lumen of the deflection member proximate to said atrial tissue site; and transmitting energy to said distal end of said elongate member through said conductor, such that said atrial target tissue is ablated, coagulated or phototherapeutically modulated without damaging surrounding tissue, thereby treating or preventing atrial fibrillation.

As noted above, neither Kittrell nor Heaven recite a method which includes introducing a maneuverable apparatus having a deflection member disposed within the first lumen of the flexible elongate member into atrial tissue. Further, neither Kittrell nor Heaven teach or suggest positioning a slidable conductor through said lumen of the deflection member proximate to said atrial tissue site.

The disclosures of Isner do not remedy the deficiencies of Kittrell and Heaven. Isner teaches introducing a catheter into the circulatory system with the distal tip of the catheter held in position within the ventricle by a preformed sigmoidal bend and a fixation wire. Nowhere does Isner teach or suggest any type of deflection member, and it naturally follows that Isner would be unable to position a slidable conductor through said lumen of the deflection member proximate to said atrial tissue site.



Accordingly, because Kittrell in view of Heaven and in further with Isner does not disclose the recitations of Applicants' claims 22 and 24, Applicants' claims 22 and 24 are allowable.

*There is no Motivation to Combine Kittrell with Heaven and further with Isner*

In addition to neither Kittrell with Heaven and with Isner teaching or suggesting all of the recitations of Applicants' claims, one having skill in the art would have no motivation to combine Kittrell with Heaven, and further with Isner. As noted above, because Kittrell already solves the problem addressed by Heaven, there would be no motivation for one skilled in the art to combine Kittrell with Heaven. Further, one having skill in the art would have no motivation to combine Kittrell with Heaven and further with Isner because the teachings of Isner are the exact opposite as those of Kittrell and Heaven.

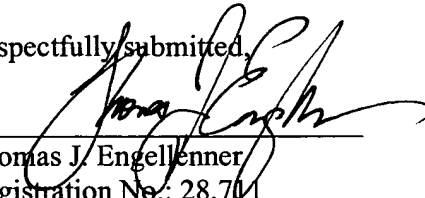
Isner teaches sliding the distal end of a catheter into a patient's heart, and moving a fixation wire proximally to the distal end of the catheter to prevent movement of the catheter during use. Thus, the fixation wire of Isner does not cause movement of the distal end of the catheter, but rather provides rigidity to the catheter to maintain the portion of the distal tip during use. [Col. 3, lns. 33-36; Col. 4, lns. 11-15.]

Accordingly, because Isner's teachings are exactly opposite those of Kittrell and Heaven, there would be no motivation for one skilled in the art to combine Kittrell and Heaven further with Isner.

Conclusion

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue. The Examiner is kindly requested to telephone the undersigned representative in the event that the amendments do not place this case in condition for allowance or if a telephone interview can otherwise expedite the prosecution of this application.

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